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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/941,997	08/29/2001	Qinwei Shi	1112-I-052CON	9957

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EXAMINER

HINES, JANA A

ART UNIT PAPER NUMBER

1645

DATE MAILED: 12/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/941,997	SHI ET AL.	
	Examiner	Art Unit	
	Ja-Na A Hines	1645	

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 29 August 2001.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) \_\_\_\_\_ is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 1-15 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \*    c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.	6) <input type="checkbox"/> Other: _____.

## DETAILED ACTION

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3 and 9 are drawn to an isolated polypeptide ~~and an expression vehicle~~, classified in class 424, subclass 548.
- II. Claims ~~4~~-8 are drawn to a polynucleotide, expression vehicle and host cell classified in class 435, subclass 91.4.
- III. Claim 10 is drawn to a method of preparing antibodies, classified in class 424, subclass 134.1.
- IV. Claim 11 is drawn to a method of purification, classified in class 530, subclass 391.1.
- V. Claims 12-13 are, drawn to calibrators and controls, classified in class 536, subclass 25.3.
- VI. Claims 14-15, drawn to a method of immuno-detection and a kit, classified in class 435, subclass 7.1.

- I. The inventions are distinct, each from the other because of the following reasons:
2. Inventions I and II, or V are unrelated. The products are distinct as claimed because they have different structures and different uses. Group I is drawn to an isolated polypeptide; Group II is drawn to a polynucleotide; while group III is drawn to calibrators and controls. Each group has a different function, effect and is capable of use without the other. For instance, the polynucleotide product of Group II has a

different structure when compared to the other groups. Each group has a different structure, produces different effects and has a different function from the other groups. Therefore, the products of the inventions are distinct as claimed.

3. Inventions III and either IV or VI are related as methods. The methods are distinct as claimed because they have different methods with different method steps; different functions and the effects have different final outcomes. Group III is drawn to a method of preparing antibodies. No other method requires the same method steps or produces the same result. For instance Group IV's method of immuno-detection allows for detection in a bodily fluid, however no other method requires such. Each group has requires additional unrelated agents, produce different effects and have different functions from any other group. Therefore, the methods of the inventions are distinct as claimed.

4. Inventions III and IV, I or VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions in Group III is a method of preparing antibodies; Group I is drawn to an isolated polypeptide; Group IV a method of purification; Group VI a method of immuno-detection and a kit. The method of preparing antibodies has a different mode of operation, function and effect since it

requires using troponin I as an immunogen, therefore when compared to the other groups it is unrelated. Thus the groups are unrelated.

5. Inventions III and I or VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different invention of Group IV is drawn to a method of purification, while Group I, III and VI are drawn to an isolated polypeptide; a method of preparing antibodies; and a method of immuno-detection and a kit. The method of purifying antibodies has a different mode of operation, function and effect when compared to the other groups, therefore it is unrelated. The method teaches purifying antibodies using the troponin fragments in an affinity chromatography assay.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

7. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II-IV, restriction for examination purposes as indicated is proper.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines *JH*  
December 9, 2002

*LFS*  
LYNETTE R. F. SMITH  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600